

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, EX REL.)	
ANTHONY R. SPAY,)	
)	
Plaintiff,)	
)	
vs.)	Case No. 09-4672
)	
CVS CAREMARK CORPORATION;)	HON. RONALD L. BUCKWALTER
CAREMARK Rx, LLC (f/k/a CAREMARK)	
Rx, Inc.); CAREMARK, LLC (f/k/a)	
CAREMARK, INC.); SILVERSCRIPT, LLC)	
(f/k/a SILVERSCRIPT INC.),)	
)	
Defendants.)	

**DEFENDANTS' ANSWER TO RELATOR'S
FIRST AMENDED QUI TAM COMPLAINT**

Defendants CVS Caremark Corporation, Caremark Rx, LLC, Caremark, LLC, and SilverScript, LLC (collectively “Caremark” or “Defendants”), by and through their undersigned attorneys, hereby answer the First Amended Qui Tam Complaint (“Amended Complaint”) brought by Plaintiff Anthony R. Spay (“Spay” or “Plaintiff” or “Relator”) and respond to the allegations as follows:

1. Defendants admit only that Plaintiff purports to bring an action to recover alleged damages and civil penalties and asserts claims under the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended (“the FCA” or “the Act”). However, Defendants deny that Plaintiff has any valid claims as against them or that Plaintiff is entitled to any of the requested relief. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 1 of the Amended Complaint.
2. Defendants deny the allegations in Paragraph 2 of the Amended Complaint.
3. Defendants deny the allegations in Paragraph 3 of the Amended Complaint.

4. Defendants deny the allegations in Paragraph 4 of the Amended Complaint.

5. Defendants deny the allegations in Paragraph 5 of the Amended Complaint.

6. Defendants admit only that Plaintiff purports to seek to recover alleged damages and civil penalties. However, Defendants deny that Plaintiff has any valid claims as against them and deny that they are liable for any such damages or civil penalties. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 6 of the Amended Complaint.

7. The allegations in Paragraph 7 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 7 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statute referenced therein.

8. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 8 of the Amended Complaint, and therefore deny the same.

9. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 9 of the Amended Complaint, and therefore deny the same.

10. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 10 of the Amended Complaint, and therefore deny the same.

11. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 11 of the Amended Complaint, and therefore deny the same.

12. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 12 of the Amended Complaint, and therefore deny the same.

13. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 13 of the Amended Complaint, and therefore deny the same.

14. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 14 of the Amended Complaint, and therefore deny the same.

15. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 15 of the Amended Complaint, and therefore deny the same.

16. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 16 of the Amended Complaint, and therefore deny the same.

17. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 17 of the Amended Complaint, and therefore deny the same.

18. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 18 of the Amended Complaint, and therefore deny the same.

19. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 19 of the Amended Complaint, and therefore deny the same.

20. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 20 of the Amended Complaint, and therefore deny the same.

21. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 21 of the Amended Complaint, and therefore deny the same.

22. Defendants admit that Defendant CVS Caremark Corporation (hereafter “CVS Caremark”) is incorporated under the laws of the state of Delaware and headquartered at One CVS Drive in Woonsocket, Rhode Island, 02895, and that, as set forth in CVS Caremark’s 2011 Form 10-K, together with its subsidiaries, it is the largest pharmacy health care provider in the United States. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 22 of the Amended Complaint.

23. Defendants admit that CVS Caremark was formed on March 22, 2007, as the result of a merger between CVS Corporation and Defendant Caremark, Rx, Inc. Defendants further admit that at the time of the merger, Defendant Caremark Rx, Inc. was merged with CVS Corporation and into a newly-formed subsidiary of CVS Corporation, with the CVS subsidiary continuing as the surviving entity. Defendants admit that following the merger, the merged company changed its name to “CVS Caremark Corporation.”

24. Defendants admit that CVS Caremark has stated following the merger of CVS Corporation and Caremark, Rx, Inc. in 2007, that, together with its subsidiaries, it is the largest

provider of prescription and related healthcare services in the United States, and that its subsidiaries fill or manage more than one billion prescriptions per year. Except as expressly admitted, Defendants deny the allegations in Paragraph 24 of the Amended Complaint.

25. Defendants admit that CVS Caremark has the two business segments identified, but deny that such segments are exclusive. Defendants further admit that, as set forth in its 2011 Form 10-K, in 2010, CVS Caremark's subsidiaries in the pharmacy services segment filled or managed approximately 585 million prescriptions, and its subsidiaries in the retail pharmacy segment filled approximately 636 million retail prescriptions, or approximately 18% of the entire U.S. retail pharmacy market. Except as expressly admitted, Defendants deny the allegations in Paragraph 25 of the Amended Complaint.

26. Defendants deny the allegations in the first sentence of Paragraph 26 of the Amended Complaint. As to the second sentence of Paragraph 26, Defendants admit only that CVS Caremark's subsidiaries operate the on-line retail website, CVS.com®, and mail order and specialty pharmacies. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 26 of the Amended Complaint.

27. Defendants admit only that certain subsidiaries of CVS Caremark Corporation (none of which are parties to this proceeding) currently own and/or operate certain retail stores, mail order pharmacies and a specialty pharmacy within the Commonwealth of Pennsylvania. Defendants deny the remaining allegations of this Paragraph.

28. Defendants admit that CVS Caremark's subsidiaries operating in its pharmacy services business offer a full range PBM services, including mail order pharmacy services, specialty pharmacy services, administration, formulary management, and claims processing,

among others, and that the largest customer in 2007 was FEHBP. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 28 of the Amended Complaint.

29. Defendants admit only that one or more of CVS Caremark's subsidiaries has been administering the retail pharmacy benefit program for the Blue Cross and Blue Shield Government-wide Service Benefit Plan (also known as the Federal Employee Program ("FEP")) since 1993. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 29 of the Amended Complaint.

30. Defendants admit only that in late 2009, one or more of CVS Caremark's subsidiaries' contract with FEP was extended through the end of 2011, and was further extended in May 2011 through 2014, with the services being provided including retail pharmacy benefit management services, including network contracting and management of customized clinical programs, as well as mail order and specialty pharmacy services. Defendants further state that such agreement speaks for itself, and deny the remaining allegations in Paragraph 30 of the Amended Complaint.

31. Defendants deny the allegations in Paragraph 31 of the Amended Complaint.

32. Defendants deny that Paragraph 32 accurately characterizes CVS Caremark's public filings, which speak for themselves, and therefore deny the allegations in Paragraph 32 of the Amended Complaint.

33. Defendants admit that certain of CVS Caremark's subsidiaries have provided Part D PBM services to their various respective clients' Part D Plans. Defendants specifically deny that Exhibit "A" attached to the Amended Complaint is an organizational chart of any Defendant describing the CVS Caremark entities involved in its Medicare Part D business. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 33.

34. Defendants admit that since 2006 SSIC has served as a PDP Sponsor that contracts with CMS to provide prescription drug benefits, and that it provides such benefits in all 50 states, District of Columbia, and Puerto Rico. Except as expressly admitted, Defendants deny the allegations in Paragraph 34 of the Amended Complaint.

35. Defendants admit that on or about January 1, 2009, Accendo replaced RxAmerica as the sponsor of a Part D drug benefit plan. Defendants deny the remaining allegations in Paragraph 35 of the Amended Complaint.

36. Defendants admit only that various subsidiaries of CVS Caremark operate thousands of retail pharmacies, as well as mail order and specialty pharmacies that process Part D prescriptions and dispense Part D drugs to Medicare beneficiaries. Except as expressly admitted, Defendants deny the allegations in Paragraph 36 of the Amended Complaint.

37. Defendants admit that SSIC is a Medicare Part D Prescription Drug Plan (“PDP”) Sponsor that provides Medicare Part D drug benefits to eligible beneficiaries, and has done so since 2006. Except as expressly admitted, Defendants deny the allegations in Paragraph 37 of the Amended Complaint.

38. Defendants admit that SSIC is a PDP that contracts with CMS to provide prescription drug plans in all 50 states, the District of Columbia, and Puerto Rico. Except as expressly admitted, Defendants deny the allegations in Paragraph 38 of the Amended Complaint.

39. Defendants admit that in December 2010 CVS Caremark announced an agreement to acquire the Medicare Part D business of Universal American Financial Corporation for approximately \$1.25 billion. Defendants further admit that the acquisition was completed on April 29, 2011. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 39 of the Amended Complaint.

40. Defendants admit that Caremark Rx, LLC is organized under the laws of the state of Delaware, with its principal offices located in Woonsocket, RI. Defendants further admit that Caremark Rx, LLC is the direct or indirect parent of CVS Caremark's various subsidiary entities that provide certain PBM services. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 40 of the Amended Complaint.

41. Defendants admit that, as set forth in Caremark Rx's 2007 Form 10-K, together with its subsidiaries, it was one of the largest pharmaceutical services companies in the United States, with net revenues in 2006 of approximately \$36.8 billion, and collectively employing approximately 13,360 people. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 41 of the Amended Complaint.

42. Defendants admit only that certain subsidiaries of Caremark Rx provide certain PBM services, including the facilitation of dispensing of prescription drugs to the eligible participants of their clients' benefit plans, and the provision of drug benefits to eligible beneficiaries under the Federal government's Medicare Part D Program. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 42 of the Amended Complaint.

43. Defendants admit only that certain subsidiaries of Caremark Rx operate mail order, specialty mail order and retail specialty pharmacy subsidiaries that conduct business in various locations throughout the United States and/or certain of its legal territories. Defendants deny the remaining allegations in Paragraph 43 of the Amended Complaint.

44. Defendants admit that CVS Caremark's subsidiaries operating in the pharmacy services segment provide a range of PBM services including mail order pharmacy services, specialty pharmacy services, administration, formulary management and claims processing,

among others, and that their clients include, but are not limited to, certain managed care entities that provide services to beneficiaries of Medicare and Medicaid, as well as employers who qualify for the retiree drug subsidiary. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 44 of the Amended Complaint.

45. Defendants admit that certain of CVS Caremark's and/or Caremark Rx's subsidiaries provide services to their respective clients (including employers, unions, government employee groups, insurance companies, and managed care organizations), some of whom have qualified as PDPs. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 45 of the Amended Complaint.

46. Defendants admit that certain of CVS Caremark subsidiaries assist employer, union, and other health plan clients that qualify for the Medicare Part D retiree drug subsidy by, among other things, collecting and submitting eligibility and/or drug cost data to CMS as required under Part D. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 46 of the Amended Complaint.

47. Defendants admit that SilverScript, L.L.C. was formerly known as SilverScript, Inc. and changed its name to CVS Caremark Part D Services, L.L.C. ("SilverScript") on or about May 28, 2009. Defendants admit that SilverScript is a Delaware limited liability company with its principal place of business at 2211 Sanders Road, Northbrook, Illinois 60062.

48. Defendants admit that SilverScript is a wholly-owned subsidiary of Caremark Rx, L.L.C. and is an indirectly owned subsidiary of CVS Caremark. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 48 of the Amended Complaint.

49. Defendants admit that since 2006, SilverScript has provided certain PBM services to Part D Plan Sponsors in various locations throughout the country, including, from 2006

through 2007, MCS Life. Defendants admit, on information and belief, that MCS is a for profit corporation registered in the Commonwealth of Puerto Rico. Except as expressly admitted, Defendants deny the remaining allegations of this Paragraph.

50. Defendants deny the allegations in Paragraph 50 of the Amended Complaint.

51. Defendants deny the allegations in Paragraph 51 of the Amended Complaint.

52. Defendants admit that SilverScript has provided PBM services to Part D Plan Sponsors, including to MCS Life, and that after March 2007 it remained a subsidiary of Caremark Rx, which was an indirect subsidiary of CVS Caremark. Except as expressly admitted, Defendants deny the remaining allegations of this paragraph.

53. Defendants admit that SilverScript provided Part D PBM services from 2006, and that in 2009, it became known as CVS Caremark Part D Services, LLC, which is a Delaware limited liability corporation with a registered agent located at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Except as expressly admitted, Defendants deny the remaining allegations of this paragraph.

54. Defendants admit that Caremark is a California limited liability company which has its principal place of business at 2211 Sanders Road, Northbrook, IL 60062, and that it is wholly-owned by Caremark Rx. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 54 of the Amended Complaint.

55. Defendants admit only that prior to the referenced merger, Caremark Rx had various subsidiaries, including but not limited to Caremark Inc. (now known as Caremark, L.L.C.) and CaremarkPCS, that provided a variety of PBM services to their respective clients. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 55 of the Amended Complaint.

56. Defendants admit that SilverScript Insurance Company offers Medicare Part pharmacy benefits. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 56 of the Amended Complaint.

57. Defendants admit that SilverScript Insurance Company was formed as an indirect subsidiary of Caremark Rx to participate as a Part D Plan under the Medicare Drug Benefit and that in 2006 it obtained a license from the State of Tennessee to operate as a health insurance company. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 57 of the Amended Complaint.

58. Defendants admit that SilverScript Insurance Company is an indirect subsidiary of CVS Caremark, offers Medicare Part D pharmacy benefits, and has been approved by CMS as a prescription drug plan Sponsor under Medicare Part D throughout the United States. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 58 of the Amended Complaint.

59. Defendants deny that SilverScript Insurance Company is a direct wholly-owned subsidiary of CVS Caremark Corporation. Defendants admit that SilverScript Insurance Company currently offers Part D Plans in all 50 states, Washington D.C. and Puerto Rico. Defendants further admit that for the year ending in 2008, SilverScript Insurance Company was licensed in Pennsylvania. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 59 of the Amended Complaint.

60. Defendants admit that SSIC and SilverScript are indirect subsidiaries of CVS Caremark. Except as expressly admitted herein, Defendants deny the remaining allegations in Paragraph 60 of the Amended Complaint.

61. Defendants deny the allegations in Paragraph 61 of the Amended Complaint.

62. Defendants deny the allegations in Paragraph 62 of the Amended Complaint.

63. Defendants deny the allegations in Paragraph 63 of the Amended Complaint.

64. The first two sentences of the allegations in Paragraph 64 of the Amended Complaint are legal conclusions to which no response is required. To the extent a response is required, Defendants deny such allegations. Defendants deny the remaining allegations in Paragraph 64 of the Amended Complaint.

65. Defendants admit, on information and belief, that Medical Card System, Inc. (hereafter, "MCS") is a for profit corporation registered in the Commonwealth of Puerto Rico. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 65 of the Amended Complaint, and therefore deny the same.

66. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 66 of the Amended Complaint, and therefore deny the same.

67. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 67 of the Amended Complaint, and therefore deny the same.

68. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 68 of the Amended Complaint, and therefore deny the same.

69. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 69 of the Amended Complaint, and therefore deny the same.

70. Defendants admit, on information and belief, that MCS Life Insurance Company (hereafter “MCS Life”) is a for profit corporation registered in the Commonwealth of Puerto Rico. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 70 of the Amended Complaint, and therefore deny the same.

71. Defendants admit, on information and belief, that MCS Life is a subsidiary of MCS. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 71 of the Amended Complaint, and therefore deny the same.

72. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 72 of the Amended Complaint, and therefore deny the same.

73. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 73 of the Amended Complaint, and therefore deny the same.

74. Defendants admit only that SilverScript entered into a contract with MCS on or about January 1, 2006 (which is a document that speaks for itself and Plaintiff’s characterization thereof is therefore denied), pursuant to which it provided certain services to MCS Life during the referenced timeframe as more specifically set forth in the referenced contract. Except as expressly admitted, Defendants deny the remaining allegations of this Paragraph.

75. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 75 of the Amended Complaint, and therefore deny the same.

76. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 76 of the Amended Complaint, and therefore deny the same.

77. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 77 of the Amended Complaint, and therefore deny the same.

78. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 78 of the Amended Complaint, and therefore deny the same.

79. The allegations in Paragraph 79 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 79.

80. The allegations in Paragraph 80 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 80 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes referenced therein.

81. The allegations in Paragraph 81 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 81.

82. Defendants deny the allegations in Paragraph 82 of the Amended Complaint.

83. The allegations in Paragraph 83 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 83 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute and regulation referenced therein.

84. The allegations in Paragraph 84 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 84 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Act or statutes referenced therein.

85. The allegations in Paragraph 85 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 85 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes referenced therein.

86. The allegations in Paragraph 86 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 86 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes referenced therein.

87. Defendants deny that all of the Defendants offer Part D Plans as alleged in Paragraph 87 of the Amended Complaint. The remaining allegations in Paragraph 87 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 87 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes referenced therein.

88. The allegations in Paragraph 88 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 88 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and regulation referenced therein.

89. The allegations in Paragraph 89 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 89 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein.

90. The allegations in Paragraph 90 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 90 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes referenced therein.

91. The allegations in Paragraph 91 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 91 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein.

92. The allegations in Paragraph 92 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 92 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and regulation referenced therein.

93. The allegations in Paragraph 93 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 93 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein, or any other applicable law or regulation.

94. The allegations in Paragraph 94 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 94 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

95. The allegations in Paragraph 95 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 95 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and regulations that govern payments from CMS to Part D Plan Sponsors and documentation of actual costs incurred by Part D Plan Sponsors, or any other applicable law or regulation.

96. The allegations in Paragraph 96 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 96 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein.

97. The allegations in Paragraph 97 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 97 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and/or regulations that govern CMS' cost reconciliation processes, or any other applicable law or regulation.

98. The allegations in Paragraph 98 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 98 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the statutes and/or regulations governing payment from CMS to a Part D

Sponsor and a Part D Sponsor's payment to pharmacies for prescriptions. Defendants further deny that Plaintiff has accurately characterized the Part D payment process and therefore deny the remaining allegations of this Paragraph.

99. The allegations in Paragraph 99 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 99 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein.

100. The allegations in Paragraph 100 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 100 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

101. The allegations in Paragraph 101 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 101 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulations referenced therein.

102. The allegations in Paragraph 102 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 102 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation or 2006 CMS Prescription Drug Manual referenced therein.

103. The allegations in Paragraph 103 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 103 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

104. The allegations in Paragraph 104 of the Amended Complaint set forth legal conclusion to which no response is required. To the extent a response is required, the referenced 2006 CMS Prescription Drug Manual is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document.

105. The allegations in Paragraph 105 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 105 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation or 2006 CMS Prescription Drug Manual referenced therein.

106. The allegations in Paragraph 106 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 106 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the 2006 CMS Prescription Drug Manual referenced therein, or any other applicable law or regulation. Defendants further state that the referenced CMS Prescription Drug Manual is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document.

107. The allegations in Paragraph 107 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 107 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation or 2006 CMS Prescription Drug Manual referenced therein.

108. Defendants admit the allegations in Paragraph 108 of the Amended Complaint.

109. Defendants admit that Part D Plan beneficiaries seeking to have their prescriptions filled have the option, among others, of going to a retail pharmacy or submitting such prescription to a mail order pharmacy. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 109 of the Amended Complaint.

110. Defendants admit that pharmacies seeking to fill a Part D Plan beneficiary's prescription will generally receive certain prescription and participant information, submit certain information to the paying entity, including so as to confirm Medicare Part D enrollment and identify applicable co-pays, and that such process typically takes place via real-time data transmissions. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 110 of the Amended Complaint.

111. Defendants admit that a pharmacy receiving a Part D prescription must perform certain pharmacy services, as required by state law. The remaining allegations of paragraph 111 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 111 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the state laws referenced therein, or any other applicable law or regulation.

112. The allegations of paragraph 112 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 112 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the law, regulation, or contract referenced therein, or any applicable law, regulation, and/or CMS guidance.

113. Defendants admit that the allegations in Paragraph 113 of the Amended Complaint generally describe certain aspects of the adjudication process with respect to network retail and mail order pharmacies. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 113 of the Amended Complaint.

114. The allegations of paragraph 114 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 114 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of any applicable law, regulation, and/or CMS guidance.

115. The allegations in Paragraph 115 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 115 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein, or any other applicable law, regulation and/or guidance.

116. The allegations in Paragraph 116 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 116 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulation(s) governing the submission of information regarding costs of providing Part D coverage by Part D Sponsors to CMS, or of any other applicable law, regulation, and/or CMS guidance.

117. The allegations in Paragraph 117 of the Amended Complaint set forth legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 117 to the extent they are inconsistent with, or are Plaintiff's

interpretation of, the text of the statute referenced therein, or any other applicable law, regulation and/or guidance.

118. Defendants admit that a PDE record contains fields for prescription drug cost and payment data as further described in CMS guidance. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 118 of the Amended Complaint.

119. The allegations in Paragraph 119 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 119 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute referenced therein.

120. The allegations in Paragraph 120 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 120 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein.

121. The allegations in Paragraph 121 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 121 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations or CMS Instructions referenced therein.

122. The allegations in Paragraph 122 of the Amended Complaint constitute a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 122 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulations referenced therein.

123. The allegations in Paragraph 123 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 123 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein.

124. The allegations in Paragraph 124 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 124 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statutes, regulations, or CMS guidance governing prospective payments from CMS to Part D Sponsors.

125. The allegations in Paragraph 125 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 125 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statutes, regulations, and/or CMS guidance governing payments to a Part D Sponsor from CMS resulting from year-end reconciliations and adjustments.

126. The allegations in Paragraph 126 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 126 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

127. The allegations in Paragraph 127 of the Amended Complaint constitute a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 127 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statutes, regulations, and/or CMS guidance governing the PDE cost and payment fields that CMS relies upon and uses in its year end reconciliation.

128. The allegations in Paragraph 128 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 128 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute or regulation referenced therein.

129. The allegations in Paragraph 129 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 129 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statute and regulation referenced therein.

130. The allegations in Paragraph 130 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 130 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

131. The allegations in Paragraph 131 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 131 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

132. The allegations in Paragraph 132 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the referenced document was issued by CMS on or about the date indicated, but deny the allegations in Paragraph 132 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the referenced 2006 CMS Instructions, which have changed over time.

133. The referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document.

134. To the extent the allegations in Paragraph 134 of the Amended Complaint set forth legal conclusions, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 134 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the referenced 2006 CMS Instructions, which have changed over time. Defendants further state that the referenced CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document.

135. Defendants admit that PBMs have used certain of the NCPDP fields included within the 37 PDE data fields described in the 2006 CMS Instructions and that NCPDP approved NCPDP version 5.1 in 1999. Defendants further state that the referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 135 of the Amended Complaint.

136. The allegations in Paragraph 136 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 136.

137. The allegations in Paragraph 137 of the Amended Complaint set forth legal conclusion to which no response is required. To the extent a response is required, Defendants admit only that Plaintiff has accurately quoted two sentences contained in the referenced 2006 CMS Instructions, however Defendants deny that such sentences are contained within Section 1.4 of such Instructions, and deny Plaintiff's characterization of those sentences. Defendants further state that the referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document.

138. The allegations in Paragraph 138 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 138 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the 2006 CMS Instructions referenced therein, or any other applicable law or regulation.

139. The allegations in Paragraph 139 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that Plaintiff has accurately characterized the text of the 2006 CMS Prescription Drug Benefit Manual referenced therein, and otherwise deny the allegations in Paragraph 139.

140. The allegations in Paragraph 140 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants admit only that Plaintiff has accurately quoted certain language contained in the referenced 2006 CMS Prescription Drug Benefit Manual, however Defendants deny Plaintiff's characterization of such language, and otherwise deny the remaining allegations of this Paragraph.

141. The allegations in Paragraph 141 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 141 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation and 2006 CMS Prescription Drug Benefit Manual referenced therein.

142. The allegations in Paragraph 142 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 142 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of CMS's Electronic Data Interchange (EDI) Agreement, or similar

document, referenced therein. Defendants state that the Court's December 20, 2012 Order noted that a violation of the EDI Agreement "does not clearly give rise to an FCA claim." (12/20/12 Order at 36 n.7.)

143. Defendants admit that from 2006 to the present, SilverScript has submitted certifications to CMS, but deny that such certifications violated any applicable law, regulation, and/or CMS guidance. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 143 of the Amended Complaint.

144. The allegations in Paragraph 144 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 144 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the law, regulation, and/or CMS guidance applicable to the allegations therein.

145. The allegations in Paragraph 145 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that Plaintiff has accurately characterized the text of the 2006 CMS Prescription Drug Benefit Manual referenced therein, and otherwise deny the allegations in Paragraph 145.

146. The allegations in Paragraph 146 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 146 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the CMS 2007 Part D Reporting Requirements referenced therein, or any other applicable law, regulation, and/or CMS guidance.

147. The allegations in Paragraph 147 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 147 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulation and 2006 CMS Instructions referenced therein, or any other applicable law, regulation, and/or CMS guidance.

148. Defendants admit the allegations in Paragraph 148 of the Amended Complaint provide an accurate general description of certain PDE fields in 2006. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 148.

149. The allegations in Paragraph 149 of the Amended Complaint constitute a legal conclusion to which no response is required. To the extent a response is required, Defendants deny such remaining allegations to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulation referenced therein.

150. Defendants admit that the cited CMS Instructions refer to field 23 of the PDE record as being a data element for an Adjustment/Deletion Code. Defendants further state that the referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 150 of the Amended Complaint.

151. The allegations in Paragraph 151 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 151 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the 2006 CMS Instructions referenced therein, or any other applicable law, regulation, and/or CMS guidance. Defendants further state that the referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of the document. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 151 of the Amended Complaint.

152. Defendants admit that the cited 2006 CMS Instructions refer to field 7 of the PDE record as “Patient Gender.” Defendants further state that the referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff’s characterization of the document. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 152 of the Amended Complaint.

153. The referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff’s characterization of the document. To the extent that the allegations in Paragraph 153 of the Amended Complaint set forth legal conclusions, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 153 to the extent they are inconsistent with or are Plaintiff’s interpretation of the text of the 2006 CMS Instructions referenced therein, or any other applicable law, regulation, and/or CMS guidance.

154. The allegations in Paragraph 154 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 154 to the extent they are inconsistent with or are Plaintiff’s interpretation of the text of the regulation referenced therein, or any other applicable law, regulation, and/or CMS guidance.

155. Defendants deny the allegations in Paragraph 155 of the Amended Complaint. Defendants further state that pharmacists generally conduct concurrent DURs for gender-related contraindications and that conducting such DURs is not always also required of PBMs.

156. To the extent that the allegations of Paragraph 156 of the Amended Complaint set forth legal conclusions, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 156 to the extent they are inconsistent with or are Plaintiff’s

interpretation of any applicable law, regulation, and/or CMS guidance. Defendants deny the remaining allegations in Paragraph 156 of the Amended Complaint.

157. Defendants admit that the cited 2006 CMS Instructions identify PDE data element field 12 as “Prescriber ID Qualifier,” the field that indicates the type of identifier that is used in field 13. Defendants further admit that the cited 2006 CMS Instructions identify PDE data element field 13 as “Prescriber ID,” and state that such field contains the prescriber’s unique identification number. Defendants further state that the referenced 2006 CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff’s characterization of the document. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 157 of the Amended Complaint.

158. To the extent the allegations in Paragraph 158 of the Amended Complaint set forth legal conclusions, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 158 to the extent they are inconsistent with or are Plaintiff’s interpretation of the text of the 2006 CMS Instructions referenced therein. As to any remaining allegations, Defendants state that the referenced CMS Instructions is a document that speaks for itself, and therefore Defendants deny Plaintiff’s characterization of the document.

159. The allegations in Paragraph 159 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 159 to the extent they are inconsistent with or are Plaintiff’s interpretation of the text of the statutes, regulations, and/or CMS guidance governing the reporting of Part D claims data as alleged. Any remaining allegations are denied.

160. The allegations in Paragraph 160 of the Amended Complaint regarding “Part D claims submitted to CMS” is vague and appears to set forth legal conclusions to which no

response is required. To the extent a response is required, Defendants deny that PDE data constitutes a “claim” under the FCA. As to all remaining allegations in Paragraph 160, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations, and therefore deny the same.

161. Defendants admit that the referenced 2006 CMS Updated Instructions state that PDE data element field 15, “Product/Service ID,” identifies the dispensed drug using a National Drug Code (NDC), which will be reported in NDC11 format. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 161 of the Amended Complaint.

162. The allegations in Paragraph 162 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 162 to the extent they are inconsistent with or are Plaintiff’s interpretation of the text of the regulation referenced therein, or any other applicable law, regulation, and/or CMS guidance.

163. The allegations in Paragraph 163 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 163 to the extent they are inconsistent with or are Plaintiff’s interpretation of the text of the 2006 CMS Instructions referenced therein or any other applicable law, regulation, and/or CMS guidance.

164. The allegations in Paragraph 164 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 164 to the extent they are inconsistent with or are Plaintiff’s interpretation of the text of the laws, regulations, and/or CMS guidance applicable to the allegations. Any remaining allegations are denied.

165. The allegations in Paragraph 165 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 165 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the laws, regulations, and/or CMS guidance applicable to the allegations. Any remaining allegations are denied.

166. The allegations in Paragraph 166 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 166 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute and regulation referenced therein.

167. The allegations in Paragraph 167 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 167 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and regulation referenced therein.

168. The allegations in Paragraph 168 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 168 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute referenced therein.

169. The allegations in Paragraph 169 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 169 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute and CMS Requirements referenced therein.

170. The allegations in Paragraph 170 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 170 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

171. The allegations in Paragraph 171 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 171 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulation referenced therein. Any remaining allegations are denied.

172. The allegations in Paragraph 172 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 172 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute referenced therein.

173. The allegations in Paragraph 173 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 173 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulations referenced therein.

174. Defendants admit that containers of prescriptions drugs pharmacists receive from manufacturers or labelers typically list the applicable NDC and the expiration date of same. The remaining allegations of Paragraph 174 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny such remaining allegations to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the federal regulations on which such allegations are based.

175. The allegations in Paragraph 175 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 175 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statute referenced therein.

176. The allegations in Paragraph 176 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 176 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations referenced therein.

177. The allegations in Paragraph 177 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the characterization of acting as "network providers" and further deny the allegations in Paragraph 177 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statutes and/or regulations on which the allegations are based or of any other applicable law, regulation, and/or CMS guidance.

178. The allegations in Paragraph 178 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 178 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the State laws on which the allegations are based.

179. The allegations in Paragraph 179 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 179 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the State laws on which the allegations are based.

180. The allegations in Paragraph 180 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 180 to the extent they are inconsistent with, or are Plaintiff's

interpretation of, the text of Section 27.19 of the Pennsylvania Pharmacy Code, or any other applicable law or regulation.

181. The allegations in Paragraph 181 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 181 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of Section 27.18 of the Pennsylvania Pharmacy Code, or any other applicable law or regulation.

182. The allegations in Paragraph 182 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 182 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of Section 27.14 of the Pennsylvania Pharmacy Code, or any other applicable law or regulation.

183. The allegations in Paragraph 183 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 183 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the Puerto Rico law cited therein, or any other applicable law, regulation, and/or CMS guidance.

184. The allegations in Paragraph 184 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 184 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Illinois law cited therein, or any other applicable law or regulation.

185. The allegations in Paragraph 185 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 185 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Illinois Pharmacy Practice Act cited therein, or any other applicable law or regulation.

186. The allegations in Paragraph 186 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 186 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Illinois law cited therein, or any other applicable law or regulation.

187. The allegations in Paragraph 187 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 187 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Illinois laws cited therein, or any other applicable law or regulation.

188. The allegations in Paragraph 188 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 188 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Illinois law cited therein, or any other applicable law or regulation.

189. The allegations in Paragraph 189 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 189 to the extent they are inconsistent with, or are Plaintiff's

interpretation of, the text of the Illinois Food Drug and Cosmetic Act cited therein, or any other applicable law or regulation.

190. The allegations in Paragraph 190 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 190 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Puerto Rico law cited therein, or any other applicable law or regulation.

191. The allegations in Paragraph 191 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 191 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Florida law cited therein, or any other applicable law or regulation.

192. The allegations in Paragraph 192 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 192 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Florida law cited therein, or any other applicable law or regulation.

193. The allegations in Paragraph 193 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 193 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Florida law cited therein, or any other applicable law or regulation.

194. Defendants admit that Part D sponsors contract with PBMs for the adjudication of Part D claims. The remaining allegations in Paragraph 194 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny those remaining allegations to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulation cited therein, or any other applicable law, regulation, and/or CMS guidance.

195. The allegations in Paragraph 195 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 195 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statutes and/or regulations on which the allegations are based, or of any other applicable law, regulation, and/or CMS guidance.

196. The allegations in Paragraph 196 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 196 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation cited therein, or any other applicable law or regulation.

197. The allegations in Paragraph 197 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 197 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation cited therein, or any other applicable law or regulation.

198. The allegations in Paragraph 198 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny the allegations in Paragraph 198 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation cited therein, or any other applicable law or regulation.

199. The allegations in Paragraph 199 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 199 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statute, regulation, and/or CMS Instructions on which the allegation is based.

200. The allegations in Paragraph 200 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 200 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulation cited therein, or any other applicable law or regulation.

201. The allegations of Paragraph 201 of the Amended Complaint are vague and susceptible to multiple interpretations, including through their use of the phrases "CMS uses" and "a 'First Data Bank' file or a similar compendium"; accordingly, no response to these allegations is required. To the extent a response is required, Defendants deny the allegations in Paragraph 201 of the Amended Complaint.

202. The allegations regarding drugs with terminated NDCs not being drugs covered under the Medicare Part D program in Paragraph 202 of the Amendment Complaint are legal conclusions to which no response is required. To the extent a response is required, Defendants deny such allegations. The remaining allegations in Paragraph 202 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 202 to the extent they are inconsistent

with or are Plaintiff's interpretation of the text of the statutes and regulations cited therein, or any other applicable law or regulation.

203. Defendants admit that expired drugs are also sometimes referred to as "terminated drugs" in certain contexts. Defendants admit that such drugs are ones whose shelf life expiration date has been met, per manufacturer notification. Defendants further admit that a terminated or inactive NDC is a national drug code which has been replaced or discontinued by the manufacturer or labeler. Defendants state that a terminated or inactive NDC does not indicate that the corresponding drug has expired. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 203 of the Amended Complaint.

204. The allegations in Paragraph 204 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 204 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statutes and regulations cited therein, or any other applicable law or regulation.

205. The allegations in Paragraph 205 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 205 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the Puerto Rico law cited therein, or any other applicable law or regulation.

206. The allegations in Paragraph 206 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 206 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the 2006 CMS Prescription Drug Benefit Manual cited therein—

which refers to expired drugs, not terminated or inactive NDCs—or any other applicable law, regulation, and/or CMS guidance. Defendants state that a terminated or inactive NDC does not indicate that the corresponding drug has expired.

207. Defendants admit that there may be health risks associated with using an expired drugs (as opposed to a drug with an expired NDC) and that an expired drug (as opposed to a drug with an expired NDC) may not be effective for the disease or condition for which it was prescribed. The allegations in the third sentence of Paragraph 207 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny such allegations to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the State pharmacy laws referenced therein, or any other applicable law or regulation. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in the last sentence of Paragraph 207 of the Amended Complaint, which allegations Defendants therefore deny. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 207 of the Amended Complaint.

208. The allegations in Paragraph 208 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 208 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the statutes and regulations on which the allegations are based, or any other applicable law, regulation, and/or CMS guidance.

209. The allegations in Paragraph 209 of the Amended Complaint set forth legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 209 to the extent they are inconsistent with, or are Plaintiff's

interpretation of, the text of the CMS Prescription Drug Benefit Manual cited therein, or any other applicable law or regulation.

210. The allegations in Paragraph 210 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 210 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and/or regulations on which the allegations are based, or any other applicable law, regulation and/or CMS guidance.

211. The allegations in Paragraph 211 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 211 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and/or regulations on which the allegations are based, or any other applicable law, regulation and/or CMS guidance.

212. The allegations in Paragraph 212 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 212 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and/or regulations on which the allegations are based, or any other applicable law, regulation and/or CMS guidance.

213. The allegations in Paragraph 213 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 213 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and/or regulations on which the allegations are based, or any other applicable law, regulation and/or CMS guidance.

214. The allegations in Paragraph 214 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 214 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation cited therein, or any other applicable law or regulation.

215. The allegations in Paragraph 215 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 215 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation cited therein, or any other applicable law or regulation.

216. The allegations in Paragraph 216 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 216 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation cited therein, or any other applicable law or regulation.

217. The allegations in Paragraph 217 of the Amended Complaint purport to characterize portions of the CMS Prescription Drug Benefit Manual, however such Manual is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of such document.

218. The allegations in Paragraph 218 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 218 to the extent they are inconsistent with, or are Plaintiff's

interpretation of, the text of the laws cited therein, or any other applicable law, regulation or CMS guidance.

219. Defendants admit that they are familiar generally with gender edits and that the National Council of Prescription Drug Programs, Inc. (NCPDP) Rejection Code 61, “Product/Service Not Covered For Patient Gender,” has been used when appropriate since 2002. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 219 of the Amended Complaint regarding other PBMs and pharmacies, and Defendants therefore deny such allegations. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 219 of the Amended Complaint

220. The allegations in Paragraph 220 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 220 to the extent they are inconsistent with, or are Plaintiff’s interpretation of, the text of the statute cited therein, or any other applicable law or regulation.

221. The allegations in Paragraph 221 of the Amended Complaint purport to characterize portions of the 2006 CMS Prescription Drug Benefit Manual; however, such Manual is a document that speaks for itself, and therefore Defendants deny Plaintiff’s characterization of such document. Further, the allegations in Paragraph 221 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 221 to the extent they are inconsistent with, or are Plaintiff’s interpretation of, the text of the statutes and/or regulations on which the allegations are based, or any other applicable law, regulation or CMS guidance. Any remaining allegations are denied.

222. The allegations in Paragraph 222 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 222 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statutes and/or regulations on which the allegations are based, or any other applicable law, regulation or CMS guidance. Defendants deny that not performing gender edits results in submitting false gender data, and otherwise deny any remaining allegations.

223. The allegations in Paragraph 223 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 223 to the extent they are inconsistent with, or are Plaintiff's interpretation or characterization of, the text of the regulation cited therein, or any other applicable law or regulation. Any remaining allegations are denied.

224. The allegations in Paragraph 224 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 224 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute and regulation cited therein, or any other applicable law or regulation.

225. The allegations in Paragraph 225 of the Amended Complaint purport to characterize portions of the 2006 CMS Prescription Drug Benefit Manual; however such Manual is a document that speaks for itself, and therefore Defendants deny Plaintiff's characterization of such document.

226. The allegations in Paragraph 226 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants

deny that Plaintiff has accurately characterized the 2006 CMS Prescription Drug Manual cited therein, and deny the allegations in Paragraph 226 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the 2006 CMS Prescription Drug Manual cited therein, or any other applicable law, regulation, and/or CMS guidance. Any remaining allegations are denied.

227. The allegations in Paragraph 227 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that Plaintiff has accurately characterized the 2006 CMS Prescription Drug Manual referenced in this section, and otherwise deny the allegations in Paragraph 227.

228. The allegations in Paragraph 228 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that Plaintiff has accurately characterized the 2006 CMS Prescription Drug Manual referenced in this section, and therefore deny the allegations in Paragraph 228. Defendants further deny the allegations in Paragraph 228 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation and statute cited therein, or any other applicable law or regulation.

229. The allegations in Paragraph 229 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that Plaintiff has accurately characterized the 2006 CMS Prescription Drug Manual referenced in this section, and otherwise deny the allegations in Paragraph 229 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the 2006 CMS Prescription Drug Manual cited therein, or any other applicable law or regulation.

230. The allegations in Paragraph 230 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that Plaintiff has accurately characterized the 2006 CMS Prescription Drug Manual referenced in this section, and otherwise deny the allegations in Paragraph 230 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the 2006 CMS Prescription Drug Manual cited therein, or any other applicable law or regulation.

231. The allegations in Paragraph 231 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny that Plaintiff has accurately characterized the 2006 CMS Prescription Drug Manual referenced in this section, and therefore deny the allegations in Paragraph 231 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the 2006 CMS Prescription Drug Manual cited therein, or any other applicable law or regulation.

232. The allegations in Paragraph 232 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 232 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation cited therein, or any other applicable law or regulation.

233. The allegations in Paragraph 233 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 233 to the extent they are inconsistent with, or are Plaintiff's interpretation of the text, of the regulations cited therein, or any other applicable law or regulation.

234. The allegations in Paragraph 234 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 234 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulations cited therein, or any other applicable law or regulation.

235. Defendants admit only that Caremark Inc. entered into a contract with Medical Card System, Inc. on or about June 1, 2003, which is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied. Defendants state that Exhibit B includes a copy of an agreement between MCS Life Insurance Company and SilverScript, Inc., which was entered into on or about January 1, 2006. Defendants state that Exhibit B further includes a copy of Amendment No. 2 to the contract between Caremark Inc. and Medical Card System, Inc. Exhibit B speaks for itself and Plaintiff's characterization thereof is therefore denied. Except as expressly admitted, Defendants deny the remaining allegations of this Paragraph.

236. Defendants admit that, for certain years, MCS Life was approved by CMS as alleged in this Paragraph, but deny the remaining allegations in Paragraph 236 of the Amended Complaint.

237. Defendants admit only that SilverScript, Inc. entered into a contract titled Managed Pharmacy Benefit Services Agreement, Medicare Part D, with MCS Life Insurance Company, effective January 1, 2006, pursuant to which SilverScript provided certain managed pharmacy benefit services to MCS Life Insurance Company in connection with its participation with the Centers for Medicare and Medicaid Services as a Part D Plan Sponsor. Defendants further state that the referenced contract is a document that speaks for itself, and therefore deny

Plaintiff's characterization of the document and otherwise deny the remaining allegations of this Paragraph.

238. Defendants deny that Paragraph 238 accurately quotes from the referenced contract. Defendants further state that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the document and otherwise deny the remaining allegations of this Paragraph.

239. Defendants deny that Paragraph 238 accurately quotes from the referenced contract. Defendants further state that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the document and otherwise deny the remaining allegations of this Paragraph.

240. Defendants deny that Paragraph 240 accurately quotes from or characterizes the referenced sections of the referenced contract. Defendants further state that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the document and otherwise deny the remaining allegations of this Paragraph.

241. Defendants admit only that Section 1.10.b., p. 12 of the referenced contract contains, among several other provisions, the excerpt Plaintiff quotes in this paragraph. Defendants further state that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the document and otherwise deny the remaining allegations of this Paragraph.

242. Defendants admit only that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the terms of such document and otherwise deny the remaining allegations of this Paragraph.

243. Defendants admit only that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the terms of such document and otherwise deny the remaining allegations of this Paragraph.

244. Defendants deny the allegations in Paragraph 244 of the Amended Complaint.

245. Defendants admit only that the referenced contract contains, among many other provisions, Section 1.8.a., which is titled Concurrent DUR Services, and related to SilverScript's and MCS's respective obligations as to such services to be provided. Defendants further state that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the document and otherwise deny the remaining allegations of this Paragraph.

246. Defendants admit only that Paragraph 246 appears to purport to characterize certain provisions contained within Section 1.8.a. of the referenced contract; however, Defendants deny that Plaintiff has accurately characterized any such provisions, and further state that the referenced contract is a document that speaks for itself. Defendants deny the remaining allegations of this Paragraph.

247. Defendants deny that Paragraph 247 of the Amended Complaint accurately characterizes SilverScript's (or any of the other Defendants') "System," and therefore deny the allegations in Paragraph 247 of the Amended Complaint.

248. Defendants deny that Paragraph 248 accurately quotes from the referenced sections of the referenced contract. Defendants further state that the referenced contract is a document that speaks for itself, and therefore deny Plaintiff's characterization of the document and otherwise deny the remaining allegations of this Paragraph.

249. Defendants admit the allegations in Paragraph 249 of the Amended Complaint.

250. Defendants admit only that SilverScript, Inc. entered into a contract with MCS Life Insurance Company on or about January 1, 2006, which is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied. Defendant further denies that Plaintiff has accurately characterized the timeframe that SilverScript's contract with MCS was in effect, and further denies the remaining allegations of this Paragraph.

251. Defendants admit only that SilverScript, Inc. entered into a contract with MCS on or about January 1, 2006 (which is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied), and that SilverScript provided services pursuant to and in accordance with such contract. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 251 relating to MCS's actions, and therefore deny the same. Defendants deny the remaining allegations of this Paragraph.

252. Defendants admit only that SilverScript, Inc. entered into a contract with MCS Life Insurance Company on or about January 1, 2006, which is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied.

253. Defendants admit only that SilverScript, Inc. entered into a contract with MCS Life Insurance Company on or about January 1, 2006, that terminated on or about December 31, 2007, which is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied. Defendants deny the remaining allegations of Paragraph 253 (including but not limited to the allegation that the referenced services were provided by any entity other than SilverScript) insofar as they have not been admitted.

254. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 254 of the Amended Complaint, and therefore deny the same.

255. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 255 of the Amended Complaint as to what Pharm/DUR's audit was "supposed to include," and therefore deny such allegations. Defendants deny the remaining allegations of this Paragraph.

256. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 256 of the Amended Complaint, and therefore deny the same.

257. Defendants admit that in or around January, 2007, MCS informed SilverScript that MCS had retained Pharm/DUR to conduct an audit. Defendants further admit that in April, 2007 SilverScript provided Pharm/DUR with Part D claims data for the MCS Life Part D participants for the calendar year 2006. Except as expressly admitted, Defendants deny the allegations in Paragraph 257 of the Amended Complaint.

258. Defendants admit the PDE data elements are collected and initially generated by the dispensing entity to the PBM, which then submits the data in PDE report format to CMS, and that the claims data provided by SilverScript to Pharm/DUR, whether the raw data initially provided to SilverScript, or the PDE report submitted by SilverScript to CMS, is the same for each affected field. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 258 of the Amended Complaint.

259. Defendants admit only that SilverScript, Inc. entered into a contract with MCS Life Insurance Company on or about January 1, 2006, which is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied. Defendants deny the remaining allegations of Paragraph 259 insofar as they have not been admitted.

260. Defendants admit the pharmacies in SilverScript's network were throughout the United States and Puerto Rico, and that SilverScript adjudicated claims for Part D prescriptions for MCS beneficiaries that were dispensed from mail order facilities located in Miramar, Florida and Mt. Prospect, Illinois, as well as from various retail pharmacies. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 260 of the Amended Complaint.

261. Defendants admit only that Pharm/DUR purported to conduct an analysis regarding MCS's Part D paid retail and mail claims data adjudicated during calendar year 2006. However, Defendants deny the accuracy or validity of any analysis conducted by Pharm/DUR. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 261 of the Amended Complaint, and therefore deny the same.

262. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 262 of the Amended Complaint as to what Pharm/DUR claims was its "next step," and therefore deny the same. Defendants deny the remaining allegations of this Paragraph.

263. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 263 of the Amended Complaint, and therefore deny the same.

264. Defendants admit only that Pharm/DUR sent certain notices and/or made other communications to certain pharmacies in Caremark's network, but lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 264 as to whether such network pharmacies had been "selected" as claimed, and therefore deny the same. Defendants further admit that a facsimile was sent by Caremark to its network pharmacies

serving MCS members, the contents of which speak for itself, and Plaintiff's characterization of the facsimile is therefore denied. Except as expressly admitted, Defendants deny the remaining allegations of this Paragraph.

265. Defendants deny the allegations in Paragraph 265 of the Amended Complaint.

266. Defendants deny the allegations in Paragraph 266 of the Amended Complaint.

267. Defendants admit only that Pharm/DUR made various communications regarding the purported results of its audit analysis. However, Defendants deny the accuracy or validity of any conclusions reached or communications made by Pharm/DUR, and otherwise deny the remaining allegations in Paragraph 267 of the Amended Complaint.

268. Defendants admit only that Pharm/DUR purported to reach certain conclusions and identify certain Part D claims that it believed were processed improperly. However, Defendants deny the accuracy or validity of any conclusions reached by Pharm/DUR, and otherwise deny the remaining allegations in Paragraph 268 of the Amended Complaint.

269. Defendants admit only that Pharm/DUR purported to reach certain conclusions and identify certain Part D claims that it believed were processed improperly. However, Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 269 of the Amended Complaint as to what Pharm/DUR's conclusions "were based upon," and therefore deny the same. Further, Defendants deny the accuracy or validity of any conclusions reached by Pharm/DUR, and otherwise deny the remaining allegations in Paragraph 269 of the Amended Complaint.

270. Defendants state that the Medicare Part D Compliance/Fraud, Waste & Abuse manual referenced in Paragraph 270 of the Amended Complaint is a written document that speaks for itself and Plaintiff's characterization thereof is therefore denied.

271. Defendants deny the allegations in Paragraph 271 of the Amended Complaint.

272. Defendants deny the allegations in Paragraph 272 of the Amended Complaint.

273. Defendants deny the allegations in Paragraph 273 of the Amended Complaint.

274. Defendants admit that during the audit period SilverScript adjudicated certain prescriptions that had physician/prescriber identifiers not associated with a particular physician/prescriber, but deny that such adjudication was improper or violated or was contrary to any Act, applicable rules and regulations, CMS guidance, or the contract between SilverScript, Inc. and MCS Life Insurance Company. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 274 of the Amended Complaint.

275. Defendants admit that during the audit period SilverScript adjudicated certain prescriptions that had physician/prescriber identifiers not associated with a particular physician/prescriber, but deny that such adjudication was improper or violated or was contrary to any Act, applicable rules and regulations, CMS guidance, or the contract between SilverScript, Inc. and MCS Life Insurance Company. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 275 of the Amended Complaint.

276. Defendants admit that during the audit period, the referenced Miramar, Florida pharmacy filled certain prescriptions for members MCS's Part D Plans, and that certain MCS claims it dispensed contained physician/prescriber identifiers not associated with a particular physician/prescriber. Defendants deny that SilverScript's adjudication of such prescriptions was improper or violated or was contrary to any Act, applicable rules and regulations, CMS guidance, or the contract between SilverScript, Inc. and MCS Life Insurance Company. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 276 of the Amended Complaint.

277. Defendants deny the allegations in Paragraph 277 of the Amended Complaint.

278. Defendants deny the allegations in Paragraph 278 of the Amended Complaint.

279. Defendants deny that Paragraph 279 is an accurate quotation, and otherwise deny the remaining allegations in Paragraph 279 of the Amended Complaint.

280. Defendants deny that Paragraph 280 is a complete or accurate quote, and otherwise deny the remaining allegations in Paragraph 280 of the Amended Complaint.

281. The allegations of Paragraph 281 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 281 of the Amended Complaint to the extent they are inconsistent with, or are Plaintiff's interpretations of, the text of the Act or the regulations referenced therein, or any other applicable law, regulation or CMS guidance. Any remaining allegations are denied.

282. The allegations in the first sentence and the reference to "Federal Regulation" in the second sentence of Paragraph 282 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny such allegations to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the Act or statutes referenced therein. Defendants admit that SilverScript, Inc. entered into a contract with MCS Life Insurance Company on or about January 1, 2006, which is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied. Defendants deny the remaining allegations of Paragraph 282 insofar as they have not been admitted.

283. Defendants deny the allegations in Paragraph 283 of the Amended Complaint.

284. Defendants deny that Plaintiff has quoted accurately Caremark's response to a Pharm/DUR audit finding, and otherwise deny the allegations in Paragraph 284 of the Amended Complaint.

285. Defendants deny the allegations in Paragraph 285 of the Amended Complaint.

286. Defendants deny the allegations in Paragraph 286 of the Amended Complaint.

287. Defendants deny the allegations in Paragraph 287 of the Amended Complaint.

288. Defendants deny the allegations in Paragraph 288 of the Amended Complaint.

289. Defendants admit only that Pharm/DUR purported to reach certain conclusions and identify certain Part D claims that it believed were processed improperly. However, Defendants deny the accuracy or validity of any conclusions reached by Pharm/DUR, and otherwise deny the remaining allegations in Paragraph 289 of the Amended Complaint..

290. Defendants deny that the allegations in Paragraph 290 of the Amended Complaint accurately characterize SilverScript's (or any of the other Defendants') statements, and Defendants therefore deny the allegations in this Paragraph.

291. Defendants deny the allegations in Paragraph 291 of the Amended Complaint.

292. The allegations in Paragraph 292 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 292 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the regulation referenced therein.

293. Defendants deny the allegations in Paragraph 293 of the Amended Complaint.

294. Defendants deny the allegations in Paragraph 294 of the Amended Complaint.

295. Defendants deny that Paragraph 295 of the Amended Complaint contains an accurate quotation from Pharm/DUR's December 2007 audit findings report, deny the accuracy

or validity of any conclusions reached by Pharm/DUR, and otherwise deny the remaining allegations in Paragraph 295 of the Amended Complaint.

296. Defendants admit only that Exhibit C to the Amended Complaint purports to reference, in part, various adjudicated and paid Part D claims associated with terminated or inactive NDCs. However, Defendants deny the remaining allegations in Paragraph 296 of the Amended Complaint.

297. Defendants deny the allegations in Paragraph 297 of the Amended Complaint.

298. Defendants deny the allegations in Paragraph 298 of the Amended Complaint.

299. Defendants deny that Paragraph 299 accurately characterizes SilverScript's (or any of the other Defendants') practices. Defendants further deny the remaining allegations in Paragraph 299 of the Amended Complaint.

300. The allegations in Paragraph 300 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 300 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute and regulation referenced therein.

301. Defendants state that the MCS formularies are written documents that speak for themselves and Plaintiff's characterization thereof is therefore denied.

302. Defendants admit only that Pharm/DUR purported to reach certain conclusions and identify certain Part D claims that it believed were processed improperly without prior authorization. However, Defendants deny the accuracy or validity of any conclusions reached by Pharm/DUR, and otherwise deny the remaining allegations in Paragraph 302 of the Amended Complaint.

303. Defendants deny the allegations in Paragraph 303 of the Amended Complaint.

304. Defendants deny the allegations in Paragraph 304 of the Amended Complaint.

305. The first sentence of Paragraph 305 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the first sentence of Paragraph 305 of the Amended Complaint. Defendants deny the remaining allegations of Paragraph 305 of the Amended Complaint.

306. Defendants admit only that Pharm/DUR purported to reach certain conclusions and identify certain Part D claims that it believed were processed improperly for quantities of drugs or days supply over the approved limit. However, Defendants deny the accuracy or validity of any conclusions reached by Pharm/DUR, and otherwise deny the remaining allegations in Paragraph 306 of the Amended Complaint.

307. Defendants deny the allegations in Paragraph 307 of the Amended Complaint.

308. The allegation that Caremark was required to conduct concurrent DUR for over-utilization is a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegation to the extent it is inconsistent with or is Plaintiff's interpretation of the text of the regulation cited or any other applicable law, regulation, and/or CMS guidance, and to the extent it is inconsistent with or is Plaintiff's interpretation of the contract between SilverScript and MCS. Defendants deny the remaining allegations in Paragraph 308 of the Amended Complaint. Defendants state that at all relevant times, Defendants properly adjudicated Part D claims, according to applicable rules and regulations, CMS guidance, and the contract between SilverScript and MCS.

309. Defendants deny that the PDE data submitted in connection with these claims required correction or notification of CMS as SilverScript properly adjudicated Part D claims

according to applicable rules, regulations, CMS guidance, and the contract between SilverScript and MCS. Defendants deny the allegations in Paragraph 309 of the Amended Complaint.

310. Defendants deny the allegations in Paragraph 310 of the Amended Complaint.

311. The allegations of Paragraph 311 of the Amended Complaint are vague and susceptible to multiple interpretations; accordingly, no response to them is required. To the extent a response is required, Defendants deny the allegations in Paragraph 311 of the Amended Complaint.

312. The allegations in Paragraph 312 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 312 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute, regulation, rule, and/or CMS guidance on which they are based, or any other applicable law, regulation, and/or CMS guidance.

313. Defendants deny the allegations in Paragraph 313 of the Amended Complaint.

314. The allegations in Paragraph 314 set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 314 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute, regulation, rule, and/or CMS guidance on which they are based, or any other applicable law, regulation, and/or CMS guidance.

315. Defendants admit that SilverScript entered into a contract with MCS on or about January 1, 2006. That contract is a document that speaks for itself and Plaintiff's characterization thereof is therefore denied. Defendants deny the remaining allegations of Paragraph 315 insofar as they have not been admitted.

316. Defendants admit only that Pharm/DUR purported to reach certain conclusions and indentify certain claims that it believed were processed improperly through the alleged failure “to apply MAC pricing to all of the MAC drugs.” However, Defendants deny the accuracy or validity of any conclusions reached by Pharm/DUR and otherwise deny the remaining allegations in Paragraph 316 of the Amended Complaint.

317. Defendants deny the allegations in Paragraph 317 of the Amended Complaint.

318. Defendants deny the allegations in Paragraph 318 of the Amended Complaint.

319. Defendants deny the allegations in Paragraph 319 of the Amended Complaint.

320. Defendants deny the allegations in Paragraph 320 of the Amended Complaint.

321. Defendants deny the allegations in Paragraph 321 of the Amended Complaint.

322. Defendants deny the allegations in Paragraph 322 of the Amended Complaint.

323. Defendants deny the allegations in Paragraph 323 of the Amended Complaint.

324. Defendants deny the allegations in Paragraph 324 of the Amended Complaint.

325. Defendants deny the allegations in Paragraph 325 of the Amended Complaint.

326. Defendants deny the allegations in Paragraph 326 of the Amended Complaint.

327. Defendants deny the allegations in Paragraph 327 of the Amended Complaint.

328. The reference to “value” in Paragraph 328 of the Amended Complaint render the allegations in that paragraph vague and subject to multiple interpretations, and, accordingly, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 328 of the Amended Complaint.

329. Defendants deny the allegations in Paragraph 329 of the Amended Complaint.

330. Defendants deny the allegations in Paragraph 330 of the Amended Complaint.

331. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 331 of the Amended Complaint as to what Pharm/DUR's audit report "was based on" or what its analysis "included," and therefore deny the same. Defendants deny the remaining allegations in Paragraph 331 of the Amended Complaint.

332. The allegations contained in Paragraph 332 purport to characterize the fields of the Prescription Drug Event ("PDE") report, the contents of which speak for itself. Defendants deny the allegations in Paragraph 332 to the extent they are inconsistent with, or are Plaintiff's interpretation of, the fields of the PDE report.

333. Defendants admit only that Part D PDE data was properly submitted by SilverScript to CMS on behalf of MCS. Except as expressly admitted, Defendants deny the allegations in Paragraph 333 of the Amended Complaint.

334. Defendants deny the allegations in Paragraph 334 of the Amended Complaint.

335. Defendants deny the allegations in Paragraph 335 of the Amended Complaint.

336. Defendants deny the allegations in Paragraph 336 of the Amended Complaint.

337. Defendants deny the allegations in Paragraph 337 of the Amended Complaint.

338. Defendants deny the allegations in Paragraph 338 of the Amended Complaint.

339. Defendants deny the allegations in Paragraph 339 of the Amended Complaint.

340. Defendants deny the allegations in Paragraph 340 of the Amended Complaint.

341. Defendants deny the allegations in Paragraph 341 of the Amended Complaint.

342. Defendants deny the allegations in Paragraph 342 of the Amended Complaint.

343. Defendants deny the allegations in Paragraph 343 of the Amended Complaint.

344. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 344 of the Amended Complaint, and therefore deny the same.

345. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 345 of the Amended Complaint, and therefore deny the same.

346. Defendants deny the allegations in Paragraph 346 of the Amended Complaint.

347. Defendants deny the allegations in Paragraph 347 of the Amended Complaint.

348. Defendants deny the allegations in Paragraph 348 of the Amended Complaint.

349. Defendants admit only that Caremark's largest customer during the year ending December 2007 was the Federal Employee Health Benefits Program. The remaining allegations in Paragraph 349 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 349 to the extent they are inconsistent with or are Plaintiff's interpretation of the text of the regulations referenced therein.

350. Defendants deny the allegations in Paragraph 350 of the Amended Complaint.

351. Defendants deny the allegations in Paragraph 351 of the Amended Complaint.

COUNT I

Violations of the Federal False Claims Act 31 U.S.C. § 3729(a)(1)(A), (2) and (3) and (7)

352. Defendants reallege and incorporate by reference their answers to the allegations contained in Paragraphs 1 through 351 of the Amended Complaint in response to this Paragraph 352.

353. Defendants admit that Plaintiff purports to assert a claim for damages and penalties as described in Paragraph 353, but Defendants deny that Plaintiff has any such claim or is entitled to any such relief, and otherwise denies the remaining allegations of Paragraph 353.

354. Defendants deny the allegations in Paragraph 354 of the Amended Complaint.

355. Defendants deny the allegations in Paragraph 355 of the Amended Complaint.

356. Defendants deny the allegations in Paragraph 356 of the Amended Complaint.

357. No answer to this paragraph is required because the Court's Order dated December 20, 2012 rejected Plaintiff's theory that Defendants fraudulently induced CMS to contract with them as a Part D Plan and/or as a Part D PBM. (12/20/12 Order at 84 n.35 ("Accordingly, the Court will not permit Plaintiff to proceed on any fraudulent inducement claim.")) To the extent a response is required, Defendants deny the allegations in Paragraph 357 of the Amended Complaint.

358. Defendants deny the allegations in Paragraph 358 of the Amended Complaint.

359. Defendants deny the allegations in Paragraph 359 of the Amended Complaint.

360. Defendants deny the allegations in Paragraph 360 of the Amended Complaint.

361. Defendants deny the allegations in Paragraph 361 of the Amended Complaint.

362. Defendants deny the allegations in Paragraph 362 of the Amended Complaint.

363. Defendants deny the allegations in Paragraph 363 of the Amended Complaint.

364. Defendants deny the allegations in Paragraph 364 of the Amended Complaint.

365. Defendants deny the allegations in Paragraph 365 of the Amended Complaint.

366. Defendants deny the allegations in Paragraph 366 of the Amended Complaint.

367. Defendants deny the allegations in Paragraph 367 of the Amended Complaint.

368. Defendants deny the allegations in Paragraph 368 of the Amended Complaint.

369. Defendants deny the allegations in Paragraph 369 of the Amended Complaint.

370. Defendants deny that there were any false claims or false certification and/or representations as alleged, and therefore deny the allegations in Paragraph 370 of the Amended Complaint.

371. Defendants admit that during the Medicare Part D annual reconciliation, overpayments by CMS to Part D Plans or Sponsors must be returned. Except as expressly admitted, Defendants deny the allegations in Paragraph 371 of the Amended Complaint.

372. Defendants deny that they improperly adjudicated any Medicare Part D claims as alleged, and therefore deny the allegations in Paragraph 372 of the Amended Complaint.

373. Defendants deny that they submitted any false PDE data to CMS as alleged, and therefore deny the allegations in Paragraph 373 of the Amended Complaint.

374. Defendants deny the allegations in Paragraph 374 of the Amended Complaint.

375. Defendants deny the allegations in Paragraph 375 of the Amended Complaint.

376. The allegations in Paragraph 376 regarding the requirements of the statute referenced set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny such allegations to the extent they are inconsistent with, or are Plaintiff's interpretation of, the text of the statute referenced therein. Defendants deny the remaining allegations of Paragraph 376.

377. Defendants deny the allegations in Paragraph 377 of the Amended Complaint.

378. Defendants deny the allegations in Paragraph 378 of the Amended Complaint.

379. Defendants deny the allegations in Paragraph 379 of the Amended Complaint.

380. Defendants deny the allegations in Paragraph 380 of the Amended Complaint.

381. Defendants deny the allegations in Paragraph 381 of the Amended Complaint.

382. Defendants deny the allegations in Paragraph 382 of the Amended Complaint.

PRAYER FOR RELIEF

WHEREFORE, Defendants deny that Plaintiff is entitled to any relief whatsoever. Defendants further request that this Court enter judgment in their favor and against Plaintiff as follows:

A. That Plaintiff takes nothing by reason of his Amended Complaint and that judgment be rendered in favor of the Defendants;

B. That Defendants be awarded their costs of suit incurred, pursuant to 31 U.S.C. § 3730(d)(4), including reasonable attorneys' fees; and,

C. For such other relief as this Court deems just and proper.

AFFIRMATIVE DEFENSES

Without admitting any of the allegations in the Amended Complaint, Defendants assert and allege the following Affirmative Defenses. By alleged the defenses below, Defendants do not in any way agree or concede that Plaintiff has properly stated any cause of action in the Amended Complaint or that Defendants have the burden of proof or persuasion with respect to any of their defenses.

First Affirmative Defense

The Amended Complaint and its purported causes of action fail to state facts sufficient to adequately plead a cause of action against Defendants.

Second Affirmative Defense

The Amended Complaint and its purported causes of action fail to meet the pleading requirements of Federal Rules of Civil Procedure 8(a) and 9(b).

Third Affirmative Defense

Plaintiff's action is barred by 31 U.S.C. § 3730(e)(4) because it is based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media; and Plaintiff is not an "original source" as that term is defined by § 3730(e)(4)(B).

Fourth Affirmative Defense

The claims asserted in the Amended Complaint are barred, in whole or in part, because Defendants acted at all relevant times in good faith and not with any improper or illegal purpose, intent or knowledge. Each and every act or omission that Defendants are alleged to have undertaken or failed to have undertaken in the Amended Complaint was done or omitted in good faith and not with any improper or illegal purpose, intent or knowledge, and in conformity with all applicable federal and state statutes, and all applicable rules and CMS guidance promulgated thereunder.

Fifth Affirmative Defense

Plaintiff's claims are barred because Defendants did not act "knowingly" as that term is defined in 31 U.S.C. § 3729(b)(1).

Sixth Affirmative Defense

Plaintiff's claims are barred because the claims allegedly presented or caused to be pretended by Defendants were not false.

Seventh Affirmative Defense

Plaintiff's claims are barred because the records or statements allegedly made, used, or caused to be made or used by Defendants were not false.

Eighth Affirmative Defense

Plaintiff's claims are barred because there was no false claim.

Ninth Affirmative Defense

Plaintiff's claims are barred because Defendants made no express or implied false certification.

Tenth Affirmative Defense

Plaintiff's claims are barred because the alleged false certifications were not a condition of payment.

Eleventh Affirmative Defense

Plaintiff's claims are barred because the allegedly false implied certifications concern a statute or regulation that does not expressly require compliance as a condition of payment.

Twelfth Affirmative Defense

Plaintiff purposely and unreasonably delayed in making known to Defendants the allegations contained in the Amended Complaint and attempting to assert those claims. This unreasonable delay has prejudiced Defendants in that evidence bearing on Plaintiff's claims may have been lost. Plaintiff's causes of action are therefore barred in whole or in part by the doctrine of laches, estoppel, waiver, ratification, and/or unclean hands.

Thirteenth Affirmative Defense

Plaintiff's claims are barred because the United States' knowledge of the alleged conduct in the Amended Complaint and/or acquiescence of such conduct defeats the elements of falsity, scienter, materiality, and causation and precludes all damages in this action.

Fourteenth Affirmative Defense

The United States directed, ordered, approved, acquiesced or ratified Defendants' conduct, and the United States is, therefore, barred from asserting any claims based thereon.

Fifteenth Affirmative Defense

Plaintiff's claims are barred because Defendants' conduct was not material to any alleged payment or receipt of money or property in connection with any alleged false or fraudulent claim.

Sixteenth Affirmative Defense

Plaintiff is not entitled to the damages or remedies he seeks.

Seventeenth Affirmative Defense

Plaintiff's claims for damages are barred because the United States has not suffered, and it will not suffer, any damages or injury to a legally protected or cognizable interest by reason of the conduct of Defendants.

Eighteenth Affirmative Defense

The United States did not rely on the alleged statements, actions, or inaction of Defendants complained of in the Amended Complaint, and Defendants' statements, actions, or inaction otherwise were not the proximate cause or cause in fact of any injury to or alleged loss by the United States.

Nineteenth Affirmative Defense

The damages alleged by Relator, if any, are the result of acts or omissions committed by third parties over whom Defendants had neither control nor responsibility, and whose actions or inactions cannot be imputed to Defendants.

Twentieth Affirmative Defense

Should Defendants be held liable for damages, which liability is specifically denied, to the extent Plaintiff seeks damages and/or penalties unrelated to or vastly greater than its actual damages, such damages or civil penalties would be unconstitutional because they would be in

violation of the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution.

Twenty-first Affirmative Defense

Plaintiff's claims for damages are barred because such damages are speculative.

Twenty-second Affirmative Defense

Plaintiff's claims are barred because Defendants have complied with all applicable laws and regulations of the federal and state governments and all applicable CMS guidance.

Twenty-third Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the learned intermediary doctrine.

Twenty-fourth Affirmative Defense

The granting of some or all of the relief prayed for in the Plaintiff's Amended Complaint would violate the First Amendment of the United States Constitution because granting such relief would punish Defendants' truthful speech.

Twenty-fifth Affirmative Defense

The claims for damages are barred due to the United States' failure to take steps to mitigate any damages suffered.

Twenty-sixth Affirmative Defense

Relator's claims are barred ,in whole or in part, because Relator and the United States would be unjustly enriched if allowed to recover any portion of the damages alleged in the Amended Complaint.

Twenty-seventh Affirmative Defense

Relator's claims are barred, in whole or in part, because Relator's claims are vexatious, frivolous, and intended only to annoy, embarrass, and harass Defendants.

Twenty-eighth Affirmative Defense

This Court lacks subject matter jurisdiction based on the doctrines of exclusive and primary jurisdiction and failure to exhaust administrative remedies.

Twenty-ninth Affirmative Defense

Relator's claims are barred in whole or in part due to a lack of standing.

Thirtieth Affirmative Defense

Defendants preserve and assert all affirmative defenses available under any applicable law. Defendants presently have insufficient knowledge or information upon which to form a belief as to whether they may have other, as yet unstated, defenses available. Therefore, Defendants reserve their right to supplement this Answer and to assert additional defenses in the event that discovery or other means indicate they would be appropriate.

WHEREFORE, Defendants deny that Plaintiff is entitled to any relief whatsoever. Defendants further request that this Court enter judgment in their favor and against Plaintiff as follows:

- A. That Plaintiff takes nothing by reason of his Amended Complaint and that judgment be rendered in favor of the Defendants;
- B. That Defendants be awarded their costs of suit incurred, pursuant to 31 U.S.C. § 3730(d)(4), including reasonable attorneys' fees; and,
- C. For such other relief as this Court deems just and proper.

Dated: February 1, 2013

/s/Robert H. Griffith

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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2013, I electronically filed the foregoing Defendants' Answer to Relator's First Amended Qui Tam Complaint using the CM/ECF system which will send notice of electronic filing to all parties as listed on the Notice of Electronic Filing. The foregoing is available for download and viewing on the ECF system.

/s/ Robert H. Griffith

Robert H. Griffith